4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2016-N-1896]

New Animal Drugs for Use in Animal Feed; Category Definitions; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of December 1, 2016, for the final rule that appeared in the <u>Federal Register</u> of August 24, 2016. The direct final rule amends the animal drug regulations by revising the definitions of the two categories of new animal drugs used in medicated feeds to base category assignment only on approved uses in major animal species. This document confirms the effective date of the direct final rule.

DATES: Effective date of final rule published in the <u>Federal Register</u> of August 24, 2016 (81 FR 57796) confirmed: December 1, 2016.

FOR FURTHER INFORMATION CONTACT: David Edwards, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6205.

SUPPLEMENTARY INFORMATION: In the <u>Federal Register</u> of August 24, 2016 (81 FR 57796), FDA solicited comments concerning the direct final rule for a 75-day period ending November 7, 2016. FDA stated that the effective date of the direct final rule would be on

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December 1, 2016, unless any significant adverse comment was submitted to FDA during the

comment period. FDA did not receive any significant adverse comments.

Authority: Therefore, under the animal drug provisions of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 354, 360b, 360ccc, 360ccc-1, and 371), and under authority delegated

to the Commissioner of Food and Drugs, 21 CFR part 558 is amended. Accordingly, the

amendments issued thereby are effective.

Dated: November 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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